

REMARKS

This application has once again been thoroughly reviewed in light of the latest and final Office Action.

The Examiner has now rejected as unpatentable under 35 U.S.C. 103(a), all of the remaining claims based upon the combination of the teachings of Alby (WO95/27444) and Errico (U.S. 5,725,528).

Applicant, through counsel, respectfully traverses this rejection and requests reconsideration thereof.

There is only a single independent claim in this application, namely claim 12, which has been extensively amended herein for purposes of clarification and to introduce additional features, all of which are within the scope of the disclosure. No new matter has been included.

Several of the features of claim 12 have been rearranged for clarification. The newly inserted features are believed to more clearly define the invention over the prior art.

Applicant in the last submission introduced four pictures in order to assist the Examiner in the understanding of Applicant's construction. These pictures, showed the different positions that the two plates may have. The fourth picture showed a rod and fixture that is not within the present description.

It should be noted that upon review of the original English specification and claims the part numbered 18 was loosely translated from the German word "klemmschraube" as an "adjustment screw", when in fact it should more properly have been referred to as a "clamping screw". Nut 24 is screwed onto this part for the purpose of clamping the parts together.

Accordingly, it has been necessary to modify the original specification and one of the dependent claims in order to conform to the correct translation.

For purposes of this discussion and comparison of the present invention and the prior art, Applicant's invention will be referred to as the BRICON SYSTEM.

The **Bricon system** includes

- a plate system 2 including longitudinal openings 4
- two spaced rotatable discs 6, 8 in each opening 4; one above the other and each having an excentric opening 10 for a bone screw 16 in the following: bore (in order not to confuse it with the openings of the plate system) - the discs are rotatable independently from each other
- multi-axial bone screws 16

The characteristic features of the Bricon system are:

- The openings of the plate system are without notches or the like and allow continuous sliding of the two rotatable discs along the plate.

- By appropriate turning the bores of a pair of discs they can be arranged a) along one axis and b) at any desired or required lateral (transverse) location in the opening. As well, the pair of discs can be slid along the opening so that the bores also can be arranged at any desired or required longitudinal location in the opening. This feature allows to position and to fix the top end of the bone screws in a vertical orientation in the plate system.
- The bone screws can be screwed into the vertebra as required resulting in possible angles deviating from the vertical direction. Because of the multi-axial feature the top resp. mounting part of the bone screws can be oriented in the vertical direction with respect to the plate system. The mounting procedure is as follows:
 - The bone screw is screwed into the bone as required. After that the bone screw part should remain as it is (apart from a possible later medical measure called distraction which is a forced move in the lengthwise direction of the vertebrae and pulls vertebrae apart from each other - after the distraction the bone screws are fixed in the distracted position so that healing occurs in this position or the vertebrae are arranged in this position. The plate system is brought into position wherein the top part of the bone screw is passed/inserted through the bores of the discs in the plate. For this purpose the top part of the bone screw can be rotated and

inclined and the discs are rotated as required until the bores are aligned with the upper screw part.

• The fixing nut is threaded on the top part of the bone screw and is screwed on the plate fixing the upper part of the bone screw and the two discs in the plate in one go.

Thus, the bone screw resp. its upper part can be slid in the opening of the plate - in the longitudinal and in the transverse directions. Since the upper part of the bone screw can be oriented vertically with respect to the plate system, this allows avoiding stresses in the lower part of the screw that already is screwed into the bone. Accordingly, the stresses in the screwed-in part and in the bone are minimum.

Since only one part, namely the top nut, is required for fixing the bone screw in the plate system this means that the surgeon can do the complete fixation in one final step. Usually more than two screws are used in such surgical operations and this one-step fixation means a lot of labour and time saving. Time is essential for several reasons, one being the time period of anaesthesia.

The **Alby system** on the other hand includes

- a plate system 7 including longitudinal openings 8
- two spaced rotatable hemispherical washers 6 in each opening 8 - each having an excentric opening for a bone screw 1 - in the following: bore (in order not to confuse it with the openings of the plate system) - the

hemispherical washers are rotatable independently from each other

- monoaxial bone screws 1

The characteristic features of the Alby system are:

- The plate system is of the Steffee plate type. Such plates are called Steffee plates or VSP (variable screw placement) plates. Such plates have nests or arcuate recesses in the longitudinal openings so that the screws are fixed in the openings and do not slide therein. Fig. 5 of Alby shows a typical representation of a Steffee plate. The Steffee plate is e.g. used in the system of US 4 836 196 which shows a device similar to that of Alby except the eccentric bore.
- The hemispherical washers cannot be turned freely once they are mounted. They are fixed in the nests - one below and the other on top of the plate. The mono-axial screw is fixed in the bone and cannot be tilted in another angle. A rotational movement of the washers results in a tilting of the plate, see Alby, page 2, lines 3 and 21. The washers cannot be moved freely in the longitudinal direction since they are positioned in the nests. For this reason also a distraction of the vertebrae is not possible wherein the bone screw is forcedly moved in the longitudinal direction. For distraction the washers would have to be moved and for this purpose the screw and washer fixations would have to be loosened and shifted by one

nest further on and fixed again. As a result the tension in the bone would be too high or too low since a continuous sliding of the screw is not possible.

Without the nests the washers would not be fixed in their position and would be drawn back from any off-set position.

- When the bone screw is screwed into the bone, the bottom hemispherical washer is mounted thereon, then the plate is set thereon and then the top hemispherical washer is placed on. Both washers have to be nested by appropriate turning and in case of the bottom washer this has to be done before placing the plate thereon. The bottom washer cannot be moved any more when the plate is on top and the top washer is nested. If the bottom washer is to be rearranged the parts above it have to be dismounted. In practice this is impossible during a surgical operation.

The top nut is for final fixation.

Since any movement of the mounted washers applies a force on the plate and on the bone screw this results in stresses in the vertebrae.

Alby like Bricon only has one fixing nut. However, the degrees of freedom of movement are far less because of the steps/nests in the plate.

The **Errico system** includes

- a rod system including coupling elements 160 and set screws 168 and transverse holes 164
- multiaxial bone screws 100

The multiaxial screws 100 have a bone screw part 102. The top part is separate. It includes the stem portion 120, further cuff 130, spacer element 150 and nut 170. The coupling element 160 is between the spacer element 150 and the nut 170.

The mounting procedure is described in column 4, line 51 to column 5, line 5:

• The bone screw part of the bone screw is screwed into the bone. Then the stem portion 120 is placed thereon in the desired angle, the cuff 130 is placed thereon and locked. The spacer element 150 is placed thereon. Then the coupling element 160 is placed thereon so that the stem extends through its hole 164. Since the cuff 130 is locked no further movement of the stem should be possible. Only a relative movement of the hole 164 and the stem in the lateral direction with respect to the rod is possible. Thus, the nut 170 is for avoiding any relative movement rather than movement of the stem.

A movement of the stem in the longitudinal direction likewise does not appear possible since it is locked by cuff 130. However, the coupling element 160 can be moved along the rod until the set screw 168 is fixed. After locking of the cuff 130 any movements of the stem out of the passing-through

position through the hole 164 will result in stresses on the bone since the top part of the screw is fixed/locked with the bottom part and thus any movements of the top part will be imparted to the one.

If the angular position of the stem 120 is to be changed the nut 170 has to be loosened/taken off, the set screw 164 has to be loosened and the coupling element 160 has to be taken off. The cuff 130 has to be loosened. Then the stem can be tilted into the desired position and all parts have to be replaced and fixed again, see Fig. 10. It has to be taken into consideration that this perhaps can be made easily on a table in case of one screw but during a surgical operation a number of screws are involved meaning that several screws are coupled with the rod. Then the parts cannot be simply mounted and dismounted several times.

The Errico system in fact has several degrees of freedom of movement. However, many screws are involved and the structure is too complex for practical use.

If the **Alby and Errico systems** are combined, great difficulties would arise:

1. Alby uses a monoaxial screw and sets the angle between screw and plate by means of eccentric bores. The setting occurs in the plane of the plate.
2. Errico uses a polyaxial screw and sets the angle by means of the screw. The setting operation is effected

below the rod. The longitudinal movement occurs along the rod. The system includes many loose parts or parts that have to be clamped, e.g. four threads. This means that during the surgical operation too many instruments are required for fastening the threads resp. parts.

The Bricon system only requires one instrument for fixation.

Furthermore, when the Alby and Errico systems are combined this will not solve the problem of stresses applied to the bone. After the fixation has been made a further movement (e.g. by moving the upper washer) will always result in a force onto the fixed screw and thus bone. If the fixation is to be loosened for changing the angle the plate has to be dismounted in order to reach the parts and loosen these for changing the angle. In case of several screws this is not any more possible since the other screws remain mounted.

With regard to the examiner's evaluation of Errico:
It is a rod system not a plate system. It is a locking nut 170 and not a disc. Locking nut corresponds to nut 24 of the Bricon system. The upper part of the bone screw is not screwed into a plate arrangement but the hole 164 of the coupling element 150 is passed through the stem 120. The lower shaft 102 is not freely movable but is fixed with the upper part (stem 120) by cuff 130 once the cuff has been locked.

Concerning the examiner's evaluation of **Alby**:

If a system is loosely arranged in a place that has nothing to do with the region where it is used (table ./, human body with blood, ...) parts can be moved which would be fixed otherwise. When the washers are not nested they can be moved. However, the plate openings are provided for nesting.

Once the lower washer and the plate are fixed or at least the plate is on top of the lower washer there is no place for applying any instrument to the lower washer for rearranging it as long as the plate is on top.

The combination of **Alby with a bone screw as used in the Bricon system:**

We still have the fixed bottom washer and the plate on top. Then the upper part of the bone screw cannot be freely tilted any more. If it is tilted a force is applied to the bottom end of the upper part that is fixed in the bottom washer and thus a stress is imparted to the bone in spite of there being a multiaxial screw involved. In particular, no continuous movement along the lengthwise direction of the plate is possible because of the nests of the plate openings.

In addition, it has to be taken into consideration that the Alby system makes use of stresses. It is stated that the washer movement and the effect of the eccentricity of its bore are to regulate the position of the plate, namely the angular

position of the plate. When the angular position of the plate is fixed the nut 10 is fixed. Applying forces for angular positioning of the plate means applying forces to the bone screw and thus to the bone.

Benefits of the **Bricon** system:

It is the Bricon system no forces have to be applied in order to arrange the upper part of the screw and the plate. This is enabled by providing the screw as multiaxial screw and then by having the two discs continuously slidable and each independently rotatable within the plate opening. For rotation of the discs no instrument is needed and no force has to be applied. The discs are provided in the plane of the plate and thus they do not interfere with any part.

For ease in visualizing the comparison between Applicant's construction and those of Alby and Errico, a Comparison Chart is attached hereto/

As stated in the previous response, Applicant's European patent was granted after consideration of the teachings of the Alby patent.

In view of the amendments and the remarks noted, *supra*, reconsideration of the final rejection application is respectfully solicited with a view to allowance of the remaining claims.

Respectfully submitted,



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Comparison Bricon versus Alby and Errico

| System | Alby | Errico | Bricon | Importance | Remarks |
|---|--|--|---|------------|---|
| Degrees of freedom / functions | | | | | |
| Screw continuously slideable in the longitudinal direction of the plate / rod | N | Y | Y | High. | <u>Alby:</u> Notching/locking required also for angle adjustment. |
| Screw continuously slideable in the transverse direction of the plate / rod | N | Limited, only via 2 nd fixation. | Y | Medium. | <u>Alby:</u> Dependent from screw angle. - <u>Errico:</u> Additional 2 nd fixation at rod required. - <u>Bricon:</u> Structure wherein lateral sliding is possible and all parts can be tightened in one fixation step. |
| Suitable for practical operation | Limited. | Limited, 3 threads required for fixing. Very expeditious and having considerable height. | Y | High. | <u>Alby:</u> Lateral sliding only possible if angle is corrected simultaneously. No independent correction possible. The lower excenter cannot be moved with reasonable effort during operation. - <u>Errico:</u> Angle of screw head has to be adjusted in advance before placing the spacer element 150. However, at that time the angle is not yet known! The system has a height that is too great. It is very complex and this cannot be reduced for making it ready for practical use. Only very exotic applications possible. |
| Undesired local high pressures between implant part areas after tightening – because of plastic deformations – and danger of loosening if pressure is large | The more continuous the sliding, the higher the pressures are. | Very high because of continuous slidability and the accompanying edge pressures. | Small, everywhere large engaging surfaces for the pressurisations – in spite of continuous slidability. | Medium. | <u>Alby:</u> Comparatively large steps are required for sliding in the lengthwise direction in order to grant stable locking at all angles. Otherwise the pressures become too high. - <u>Errico:</u> The local pressures at the slot edges of the spacer element 150 and at the rod fixation are high. |
| Undesired stresses in vertebral column | High. | High. | Small. | High. | <u>Alby:</u> The plates cannot be bent laterally. Use of monoaxial screws accordingly results in high stresses. - <u>Errico:</u> The local pressures should be small (by theory). However, since the adjustment angle of the screw head is not known in advance, handling is very difficult. Proceeding should be iterative (approaching in steps) but this is impossible when the surgeon has to mount 6 screws – no extra time spared for this). In addition, when the height is not suitable and the screw has to be further screwed in or out this automatically involves change of the screw head angle! |
| Number of instruments | Medium. | High. | Small. | Medium. | |